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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,131	11/22/2000	Ralph L. Bass	1136/8	2281

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VB
EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/23/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,131

Applicant(s)

BASS, RALPH L.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101/112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-42 are rejected under 35 U.S.C. 101 because the claimed invention lacks credible utility.

The claimed method as is now amended is the alleviation of HIV infection by administration of sodium chloride to an HIV infected human. Despite the fact that more than a decade has past since the first cluster of cases of AIDS, neither a cure nor effective vaccine has been developed with treatment requiring compliance with multiple drug regimens (See Cecil Textbook of Medicine, Vol. 2 (21st Ed., 2000), pg. 1889). Further, it is generally accepted that the goal of anti-HIV therapy should ideally be to completely inhibit replication (Id. at 1934). The specification does not appear to show any working examples which show effective treatment of HIV in mammals much less humans. The examples which are provided appear to be hypothetical statements of what would occur as opposed examples of effective treatment in actual patients. Further, Applicant's argued but not disclosed mechanism by which administration of sodium chloride results in reduction HIV appears to be unsupported by evidence showing that the disclosed effective levels of NaCl would be sufficient to alleviate HIV. Applicant indicates that the administration should result in circulating levels of NaCl

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within the range of about 0.05 μ M to about 1.0 μ M and that the extra amount of NaCl will disrupt the HIV virus. In Hrinda et al. (US Pat. 5,661,023) it is disclosed that NaCl concentrations as high as 1.4 M for prolonged periods, such as greater than 18 hours, only resulted in partial disassembling of HIV particles with dilution to 0.25M being sufficient to prevent the same (Hrinda et al., Column 8, lines 51-68, Column 9, lines 1-12). Thus, it appears that the effective amount of NaCl needed to disrupt the HIV virus far exceeds what is disclosed and claimed as being the effective therapeutic range as well as the level of NaCl which would be considered to be safe in humans (See generally Drug Facts and Comparisons (54th Ed., 2000), pg. 116; Martindale (30th Ed., 1993), pg. 862; Specification, Pgs. 12, 13). As such, in light of the above, it appears that the claimed alleviation of HIV infection in a human infected with HIV by administration of NaCl, while appearing to have specific and substantial utility, lacks credible utility.

Claim 35 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for administration orally, sublingually, buccally and combinations thereof, does not reasonable provide enablement for transdermal administration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with said claim.

Transdermal administration is through the skin, however, the claimed method is administering to the upper gastro-intestinal tract which has no skin but mucous membranes. The specification does appear to show how a skilled artisan would administer sodium chloride in the upper GI tract transdermally when there is no skin in the upper GI tract. Further, it is uncertain how sufficient sodium chloride could be administered transdermally. See Dermatology Times

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(Nov. 1996), pp. S20 (no transdermal uptake of sodium chloride from salt baths). As such, it appears that one of ordinary skill in the art would be required to do undue experimentation in order to make and/or use the invention commensurate in scope with the claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

August 22, 2002


JOHN PAK
PRIMARY EXAMINER
GROUP 1200

